

### REMARKS

Claims 1 and 16-21 are currently pending in the application. Claims 1, 16 and 19 are in independent form.

The Office Action states that claims 1 and 16-21 contain new matter, which was not present in the 09/159,626 application, because of the inclusion of the phrase "anti-adhesion activity against *H. pylori*." It is respectfully submitted that in the Summary of the Invention of the 09/159,626 application, now U.S. Patent No. 6,303,125, there is disclosed that the fraction exhibits adhesion inhibitory activity against P fimbriated bacteria, oral bacteria, as well as reversal of aggregation/adhesion of oral bacteria and adhesion inhibitory activity against *Helicobacter pylori*. This is further supported by the Detailed Description of the Invention on page 8, lines 9-15 that discloses, "Further, the invention includes a method of inhibiting interbacterial adhesion including mucosal adhesion of *Helicobacter pylori*." Reconsideration of the objection is respectfully requested.

The Office Action states that claim 16 is objected to because of a typographical error. The typographical error has been corrected herewith and reconsideration of the rejection is respectfully requested.

Claims 1 and 17-21 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action states that in claims 1 and 19, the molecular weight limitation is indefinite. In order to further prosecution, the claims have been amended to more specifically define the molecular weight and reconsideration of the rejection is respectfully requested.

Claim 16 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In order to overcome the present

rejection, specific composition structure has been included in claim 16 and reconsideration of the rejection is respectfully requested.

Claims 1 and 16-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Ofek, et al. reference. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Ofek, et al. reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Ofek, et al. reference discloses a water-eluted fraction isolated from cranberry/blueberry juices that appears to be identical to the composition presently claimed and which possesses pharmaceutical activity. More specifically, the Office Action states that the Ofek, et al. composition is isolated from blueberry juices, thus demonstrating its compatibility in a fruit juice composition. The Office Action states that the Ofek, et al. reference specifically recognizes that "cranberry juices" are recommended by physicians to prevent and treat urinary infections (see Ofek at pages 179-180) and that fortified food compositions are conventionally known in the art and that one of ordinary skill in the art would be motivated to formulate a fruit juice product which is fortified or enriched with the patented composition, in order to obtain the benefits therefrom, thereby rendering the presently pending independent claims obvious.

However, when read more specifically, the Ofek, et al. reference confirms that fructose inhibits adhesion of *E.coli*. The specificity of *E.coli* adhesion is different from that of oral bacteria. This is specifically set forth on Page 29, lines 16-25. For example, many of the characterized oral adhesins are resistant to mannose while being sensitive to galactose or other carbohydrates. It is therefore impossible to infer from the inhibition studies performed with *E. coli*, the behavior of a cranberry preparation in tests that involve oral bacteria. Additionally, as set forth in the present application on Page 30, line 1-23, PF-1 was tested for its ability to inhibit or to reverse the coaggregation of selected bacterial pairs. The juice- derived material did not reverse the coaggregation of some of the bacterial pairs tested. This indicates that there is a specificity of the inhibitor that cannot be determined on its face. Therefore, the fact that the Ofek, et al. reference disclosed the use of a similar composition on *E. coli* is in no way indicative of how this composition would work with other bacterium.

Additionally, as set forth in the application on page 14, lines 21-25, the isolated adhesion inhibitory fraction PF-1 is insoluble in butanol and ethylacetate and is acid precipitable. This means it can be redissolved in water without loss of activity. However, the fraction loses partial activity upon heating in acidic solutions. The fraction also has a positive reaction in a phenol-sulfuric acid test as described in the examples of the present application. There is no indication that merely introducing this composition to a juice composition would be as simple as indicated in the Office Action. It is not readily apparent that the inhibitor of the presently pending independent claims can be readily placed in any fruit composition. Therefore, the Ofek, et al. reference does not disclose the composition of the presently pending independent claims.

Claims 1 and 16-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ofek, et al. reference in view of the Walker, et al. patent.

Reconsideration of the rejection under 35 U.S.C. §103(a) over the Ofek, et al. reference patent in view of the Walker, et al. patent, as applied to the claims is also respectfully requested.

It is Hornbook Law that before two or more references may be combined to negative patentability of a claimed invention, at least one of the references must teach or suggest the benefits to be obtained by the combination. This statement of law was first set forth in the landmark case of Ex parte McCullom, 204 O.G. 1346; 1914 C.D. 70. This decision was rendered by Assistant Commissioner Newton upon appeal from the Examiner-in-Chief and dealt with the matter of combination of references. Since then many courts have over the years affirmed this doctrine.

The applicable law was more recently restated by the Court of Appeals for the Federal Circuit in the case of ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572,1577, 221 U.S.P.Q. 929 (Fed. Cir. 1984). In this case the Court stated, on page 933, as follows:

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under Section 103 teachings of references can be combined only if there is some suggestion or incentive to do so. The prior art of record fails to provide any such suggestion or incentive. Accordingly we hold that the court below erred as a matter of law in concluding that the claimed invention would have been obvious to one of ordinary skill in the art under section 103."

This Doctrine was even more recently reaffirmed by the CAFC in Ashland Oil, Inc. v. Delta Resins and Refractories, Inc., et al., 776 F.2d 281,297, 227 U.S.P.Q. 657,667. As stated, the District Court concluded:

"Obviousness, however, cannot be established by combining the teachings of the prior art to produce the claimed invention unless there was some teaching, suggestion, or incentive in this prior art which would have made such a combination appropriate."

The Court cited ACS Hospital Systems, Inc. in support of its ruling. This Doctrine was reaffirmed in In re Deuel, 34 USPQ2d 1210 (Fed. Cir. 1995).

As stated above, the Ofek, et al. reference does not disclose or suggest the composition of the presently pending independent claims.

Additionally, the Office Action states that the Walker, et al. patent suggests the use of the composition as a food supplement. The extract is made from the Vaccinium plant and possesses antibacterial properties similar to those presently claimed. However, when read more specifically, the food supplement being referred to in the Walker, et al. patent is a powder product as set forth in column 12, lines 1-2. The powder can be added to food at the individual's desire. Therefore, the problems set forth above with regard to heating and high acidic solutions can still occur. The Walker, et al. patent does not disclose how such problems can be overcome. The Walker, et al. patent merely discloses that they can make a powder of this extract. There is no disclosure of how it can be used or how it can be incorporated into a fruit juice for use in oral hygiene administration. Further, there is no disclosure of the combination of the Walker, et al. reference with the Ofek, et al. reference. Absent such a disclosure, there is no teaching for, or a suggestion to combine such references. Accordingly, reconsideration of the rejection is respectfully requested.

Claims 1 and 16-18 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,840,322. An executed terminal disclaimer is enclosed herewith for overcoming the rejection. Reconsideration of the rejection is respectfully requested.

Claims 1 and 16-21 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,303,125. A properly executed terminal disclaimer is enclosed herewith,

thereby rendering the present rejection moot. Reconsideration of the objection is respectfully requested.

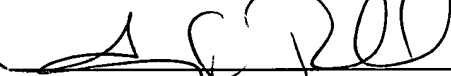
The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC



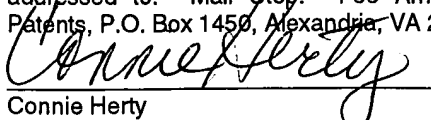
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Dated: February 16, 2004

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